Rejections Under 35 U.S.C. § 112

Claims 1-14 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Within the Office Action it is specifically stated that there is no support in the originally filed disclosure for 1) each of two lasers generating pulses to generate ablation, nor 2) combining the pulses of two laser sources to form a predetermined coagulation depth.

The applicant respectfully disagrees. In the specification, it is specifically stated that

1) A dual mode laser delivery system provides a controllable depth of both ablation and coagulation of an area of skin to be treated. The laser delivery system preferably includes a laser source having a short penetration depth. The controllable ablation depth is achieved by providing an appropriate series of pulses from the laser having an energy and exposure time to achieve ablation of the exposed area of skin to the desired depth. Once ablation of the skin has been performed, a coagulation region to the desired coagulation depth is then generated within the remaining exposed layer of skin by preferably applying a series of one or more very short non-ablative laser pulses at a high repetition rate in order to raise the temperature of the surface of the skin to a desired temperature for a period of time. [Specification, Page 4, lines 21-30 and Page 5, line 1]

2) The laser system of the preferred embodiment of the present invention is schematically illustrated in Figure 3. The laser generation system housing 30 includes the laser source 31 from which the laser beam 37 is provided. The laser source 31 preferably includes two erbium lasers 32 and 34 which generate the laser beams 33 and 35, respectively. Alternatively, any other appropriate short penetration length laser source can be used within the system of the present invention. The two laser beams 33 and 35 are combined into a single laser output 37 by the galvanometer 36 which switches between the two laser outputs 33 and 35. The galvanometer 36 then provides the laser output 37 from the laser source 31. [Specification, Page 7, lines 8-15]

The independent Claim 1 recites a medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the

laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in an ablation mode. The independent Claim 1 finds clear support for the recitation of the laser source comprising two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation mode when the laser source is in an ablation mode, in the above quoted passages and throughout the originally filed specification.

The independent Claim 11 recites a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. The independent Claim 11 finds clear support for the recitation of the two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth, in the above quoted passages and throughout the originally filed specification.

Claims 2-10 are all dependent from the independent Claim 1 and Claims 12-14 are all dependent from the independent Claim 11. For all of the reasons stated above, rejection of Claims 1-14 under 35 U.S.C. 112, first paragraph is not appropriate and should be withdrawn.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 17 and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). The Applicants respectfully traverse this rejection. No description to the teachings of Dwyer or detailed reasons for the rejection is given within the Office Action and the teachings of Dwyer have been fully characterized in the prior communications.

Briefly, Dwyer teaches a laser device that switches between a first laser beam with a first set of laser conditions and a second laser beam with a second set of laser conditions. Dwyer teaches that by manipulating the optics within the cavity of a Nd:YAG laser, the most probable lasing transition producing laser light 1.06 microns, can effectively be shut off such that lasing can occur to produce laser light at 1.3 microns. [Dwyer, Abstract] In other words, Dwyer teaches a laser device with a tunable laser cavity for switching between two lasing conditions and

thus producing two wavelengths, only one of which is generated under any one set of laser conditions.

Dwyer also teaches that a system can have two lasers with one of the lasers operating at 1.06 microns and the other laser operating at 1.3 microns, such that a surgeon can switch between the two lasers for cauterizing and cutting, respectively. However, Dwyer does not teach using one or more lasers pulsed in different ways to produce different tissue effects that are combined into a single laser beam to produce ablative and non-ablative laser pulses in a controlled fashion. In fact Dwyer does not teach combining laser beams at all.

In contrast to the teachings of Dwyer, the instant invention is directed to a laser system that is capable of operating in an ablation mode and a coagulation mode by using two or more laser sources operating at the same wavelength, which are combined into a single laser beam having a single wavelength, and wherein the pulse sequences are selectable to achieve the effects of ablating tissue or coagulating tissue. No where is this taught in the prior art. These and other features are clearly recited in the independent Claims 17 and 41.

Specifically, the independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of laser pulses each having a strength and a duration. The medical laser delivery apparatus comprises a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated. The laser delivery apparatus further comprises a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has two or more lasers which are combined into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses. The dual mode medical laser system comprises a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set laser pulses, means to alternate between pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output and means to direct the single laser output to the region of the target tissue. As discussed above, Dwyer fails to teach or suggest first laser and a second laser for generating a first set of laser pulses and a second set laser pulses, means to alternate between pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output and means to direct the single laser output to the region of the target tissue. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 6-8, 11-14, 17-19, 41 and 43-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and, the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereinafter "Dwyer"). The Applicant respectfully traverses this rejection.

A prima facie case of obviousness, warranting the combination of these five (5) references has not been set forth within the Office Action. Within the Office action, it is stated that the combination of these references would render a device more versatile and no extra cost, since the particular laser parameters claimed produce no unexpected results. However, as stated previously, the combination of features in the above cited references taken singularly or in combination, do not teach or suggest the claimed invention.

Further, in order to combine references to support a prima facie case of obviousness, there must be some suggestion or motivation to modify a reference or combine the references, there must be a reasonable expectation of success and the references must teach all of the claimed elements. The Applicant finds no suggestion within the references themselves or within the general knowledge of the art to combine such a large number of references. (M.P.E.P. 2124).

The teachings of Sklar have been fully characterized in previous communications. Briefly, the teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patient's movement while the surgeon is trying to find the target and react to the target recognition by firing the laser." [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar, column 2, lines 39-43]

Sklar does not teach or make obvious a laser device, or a laser system, with a laser source having two or more lasers that produce laser beams and which are alternated and combined to generate a single laser output for producing coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17. Nor does Sklar teach or make obvious a laser device, or a laser system, for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Sklar does not teach or make obvious an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue.

Dew does not teach or make obvious a laser source with two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41.

Further, Dew does not teach or make obvious an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach or make obvious a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers for generating a plurality of coagulative laser pulses.

Belkin does not teach or make obvious a laser or a laser system with a laser source having two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Belkin does not teach or make obvious an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Belkin teach or make obvious a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach or make obvious a medical laser with a laser system as currently claimed. Specifically, Anderson does not teach or make obvious laser source with two or more lasers that produce laser beams which are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17, or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Anderson does not teach or make obvious an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Anderson teach or make obvious a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Dwyer teaches a laser device which uses a means for switching the laser output between two laser wavelengths. The means for switching includes a prism which effectively bleeds the cavity from a dominant laser wavelength such that conditions for stimulated emission transitions producing laser light at 1.3 micron is achieved. [Dwyer, Abstract] In each case, the laser device

is producing only one wavelength for any one set of laser conditions. Dwyer, however does not teach combining two or more lasers to generate a single laser output or laser beam as taught and claimed in the instant application.

As stated above, the current invention is a laser system that utilizes multiple lasers which produce multiple laser beams. The multiple laser beams are alternated with a galvanometer or other suitable device to produce a single laser output which generates coagulation laser pulses. The laser system preferably also is configured to generate ablation laser pulses. The single laser output is preferably guided to a target tissue through an articulated arm with a series of refocussing optics. The system preferably has a user interface that allows a user to select laser pulse patterns, target sizes and operating modes. The interface preferably is a graphical user interface that displays the selected laser pulse pattern and allows the user to select a desired ablation depth value and coagulation depth value. The combinations of features claimed in the instant application are neither taught or suggested by Sklar, Dew, Belkin, Anderson, Dwyer nor their combination.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The system has a laser source for generating a series of one or more non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers for generating two or more corresponding laser beams which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a medical laser with a laser source with two or more lasers which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to medical laser having a laser source having two or more lasers which are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. The medical laser of Claims 11 also has a laser control system coupled to the laser source for controlling the laser source to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a medical laser with a laser source with two or more lasers which are combined in an alternating fashion for generating a laser output to generate a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus has a laser source having two or more lasers which are combined in an alternating fashion into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. The apparatus also has a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a medical laser delivery apparatus which has two or more lasers which are combined in an alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pluses followed by coagulation laser pulses to the region of target tissues. The dual mode medical laser system has a laser source comprising a first laser and a second laser for generating a first laser beam and a second laser beam at a same wavelength and a means to alternate between the first laser beam and the second laser beam to provide a single laser output to provide the ablation laser pulses and the coagulation laser pulses. The medical laser system also has a means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a medical laser delivery apparatus having a first and second laser that produce laser beams that are alternated to produce ablation and coagulation laser pulses from a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 43-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 43-49 are all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10, 20-24 and 42 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer") and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa").

Assa teaches an apparatus for delivering energy with a continuous output and can not be combined with Sklar, Dew, Belkin, Anderson or Dwyer either singularly or in combination to teach the combination of features taught and claimed in the instant application. Again, the inordinate number of combined references is inconsistent with establishing a prima facie case of

obviousness and there is no hint, teaching or suggestion in the prior art to combine the references in a way which would produce the invention as claimed in the instant application.

Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 4, 5, 9 and 10 are all allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 20-24 are all allowable as being dependent upon an allowable base claim.

Claim 42 is dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claim 42 is allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (408) 530-9700 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
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CERTIFICATE OF MAILING (37 CFR § 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington D.C. 20231

HAVERSTOCK & OWENS LLP.

Date: 4-28-03 By: